

REMARKS

In the OFFICE ACTION dated March 22, 2004, claims 1-10 and 23-29 were rejected as being non-enabled under 35 USC 112, first paragraph. Applicant amends the claims to more particularly point out the invention. The present invention, as now claimed, is directed to a "composition of matter." The claimed composition of matter includes a liposome having an exterior surface on which a plurality of targeting agents are attached via conjugation agents to provide targeting of the liposome to an ocular cell. The composition of matter further includes at least one "gene" located in the internal compartment of the liposome. The "gene" is defined as being able to express a therapeutic or diagnostic agent for the ocular cell. Claims 23 and 24 simply add a pharmaceutically acceptable carrier, such as saline, to the composition of matter.

The term "eye specific therapeutic gene" was coined by applicant and presented in paragraph 39 as being a particular type of "therapeutic gene." "Therapeutic gene" is another term created by applicant to broadly cover genes that express both therapeutic and diagnostic agents that, in the case of an "eye specific therapeutic gene," are specific for the eye. It is clear from the specification that applicant is not using the term "therapeutic gene" to require that the gene actually be demonstrated conclusively to have therapeutic or diagnostic value. Instead, applicant has used this term to provide guidance to one of ordinary skill regarding which types of genes are suitable for use in making liposomes in accordance with the present invention.

At least 16 different examples of genes are listed in paragraph 39 that express exemplary therapeutic and diagnostic agents that are used in investigating and treating ocular cells. This provides more than enough enabling guidance for one of ordinary skill to make the composition of matter as now claimed. One of ordinary skill in the art is well aware of the many different genes that express therapeutic or diagnostic agents which are known to be useful or potentially useful in investigating and treating ocular cells either *in vivo* or *in vitro*. Accordingly, nothing other than routine experimentation is

required in order to **make** the claimed invention. It should be noted that claim 3 specifically claims 16 genes that can be located in the internal compartment of the liposome. One of ordinary skill in the art would have no problem using one or more of these 16 specific genes to make liposome compositions in accordance with the present invention.

In order to overcome any possible misinterpretation of the terms created by applicant as discussed above, applicant amends the claims to remove the use of the term “eye specific” or “eye specific therapeutic” gene and substitutes in its place a “gene that expresses a therapeutic or diagnostic agent for said ocular cell.” This is intended to more particularly point out the types of genes that are contemplated to fall within the scope of the present invention without using the terms created by applicant.

There is also no unpredictability with respect to **use** of the claimed invention. It is important to note that applicant is not claiming a method of delivering genes to ocular cells for diagnosis or therapy. These types of method or process claims (11-22) were withdrawn from consideration and cancelled by applicant as being drawn to a non-elected invention. Since applicant is not claiming diagnostic or therapeutic uses of the composition, there is no requirement under 35 USC 112 to enable such non-claimed uses. The terms “therapeutic” and “diagnostic” are only used in the claims to provide guidance (via the specification) as to what types of genes are present in the claimed composition. Applicant is only required to teach one of ordinary skill how to use the claimed composition of matter. The specification provides more than adequate guidance on how to use the composition. For example, it can be simply mixed with ocular cells *in vitro* or combined with a suitable carrier and injected intravenously for *in vivo* delivery of the gene to ocular cells. Whether the final outcome of such use is diagnostic, therapeutic or even deadly to the ocular cell is irrelevant with respect to the claimed invention.

The claims, as now amended, are intended to focus more particularly on the fact that applicant is claiming a composition of matter that has a wide variety of existing and potential future uses with respect to delivering genes to ocular cells. The amended claims

are intended to point out that applicant is not claiming use of the composition for any particular purpose – be it diagnostic, therapeutic or anything else. Accordingly, there is no basis for requiring that the non-claimed uses of the composition as a diagnostic or therapeutic tool be enabled in accordance with 35 USC §112, first paragraph.


Claims 1-10 and 23-29 were also rejected under 35 USC §112, second paragraph, as being indefinite. Applicant amends the claims to delete the term “eye-specific gene” from the claims and substitutes in its place “a gene that expresses a therapeutic or diagnostic agent for said ocular cell.” As discussed above, the types of genes that express therapeutic and diagnostic agents for the eye are described in the specification at paragraph 39. Claim 5 has also been amended to provide the proper antecedent basis for the encapsulated gene.

Applicant respectfully requests that this application be reconsidered in view of the above amendments and remarks and that the claims, as now amended, be allowed.

Please charge any fees that may be due for the filing of this AMENDMENT AFTER FINAL or credit any overpayments to Deposit Account No. 50-1811.

Respectfully Submitted,

Dated: June 08, 2004


David J. Oldenkamp, Reg. No. 29,421
SHAPIRO & DUPONT LLP
233 Wilshire Boulevard, Suite 700
Santa Monica, California 90401
(310) 319-5411 (Telephone)
(310) 319-5401 (Facsimile)